Terrestrial Animal Health Standards Commission Report September 2016

CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

Article 12.10.1.

General provisions

~~Most glanders susceptible animals are equids.~~ Equids are the major hosts and reservoirs of glanders although s~~S~~cientific data are not available ~~for~~ on the occurrence of *infection* in zebras. Camelids and various carnivores including bears, canids and felids can also be infected but play no significant ~~epidemiological~~ role in the epidemiology of the *disease*. Glanders is a significant and potentially fatal zoonotic disease ~~with fatal outcome if not treated in a timely manner~~.

For the purposes of the *Terrestrial Code*, glanders is defined as an *infection* of equids with *Burkholderia mallei* ~~in an equid~~ with or without the presence of clinical signs.

~~The chapter deals not only with the occurrence of clinical signs caused by *B. mallei*, but also with the presence of *infection* with *B. mallei* in the absence of clinical signs.~~

The following defines the occurrence of ~~an~~ *infection* with *B. mallei*:

1) *B. mallei* has been isolated from a sample from an equid; or

2) antigen or genetic material specific to *B. mallei* has been identified in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei*; or

3) antibodies specific to *B. mallei* have been identified by a testing regime appropriate to the species in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei.*

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* is six months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 12.10.2.

Country or zone free from infection with *B. mallei* ~~infection~~

A country or a *zone* that does not comply with the point 1 *a)* of Article 1.4.6. may be considered free from *infection* with *B. mallei* when:

1) ~~glanders~~ *infection with B. mallei* ~~is~~ has been a *notifiable disease* in the entire country for at least the past three years;

2) ~~either:~~

   ~~a)~~ there has been no *case* ~~*outbreak* and no evidence~~ of *infection* with *B. mallei* ~~in equids~~ during the past three years~~, following the destruction of the last *case*; or~~

~~3b)~~ ~~no evidence of *infection* with *B. mallei* has been found during the past six months following the destruction of the last *case*; and there is~~ a *surveillance* programme ~~in place demonstrating the absence of *infection*~~ in accordance with Article 12.10.8. has demonstrated no evidence of *infection* with *B. mallei* in the past ~~12~~ six months;

~~AND~~

~~4~~3) imports of equids and their germplasm into the country or *zone* are carried out in accordance with this chapter.

Article 12.10.3.

Recovery of free status

When a *case* is detected in a previously free country or *zone*, freedom from *infection* with *B. mallei* can be regained after the following:

1) a standstill of movements of equids and their germplasm from *establishments* ~~affected~~ infected or suspected of being ~~affected~~ infected has been imposed until the destruction of the last *case*;

2) an epidemiological investigation (trace-back, trace-forward), including ~~investigations~~ to determine the likely source of the *outbreak,* ~~have~~ has been carried out;

3) a *stamping-out policy,* which includes at least the destruction of all infected equids and cleansing and *disinfection* of the ~~affected~~ infected *establishments,* has been applied;

4) increased *surveillance* in accordance with Article 12.10.8. has been carried out and has demonstrated ~~not detected any~~ no evidence of *infection* in the six months after ~~*stamping-out*~~ *disinfection* of the last infected *establishment* and during that period measures have been in place to control the movement of equids.

~~5) measures are in place to control the movement of equids to prevent the spread of *B. mallei.*~~

When the measures above are not carried out, Article 12.10.2. applies.

Article 12.10.4.

Recommendations for importation of equids from countries or zones free from infection with *B. mallei* ~~infection~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) either:

   a) was kept for six months prior to shipment, or since birth, in a ~~the *exporting*~~ *country* or *zone* free from *infection* with *B. mallei*; or

   b) was ~~imported in accordance with Article 12.10.5.,~~ kept in an *establishment* in the *exporting country* for at least 30 days and then ~~was~~ subjected to a ~~prescribed~~ test with negative result ~~on a sample taken during the 10 days prior to shipment~~.

Article 12.10.5.

Recommendations for importation of equids from countries or zones ~~considered infected~~ not free from infection with *B. mallei*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) was kept for six months prior to shipment, or since birth, in an *establishment* where no *case* of ~~glanders~~ *infection* with *B. mallei* was reported during the ~~six~~ 12 months prior to shipment;

3) was isolated and subjected to two ~~a prescribed~~ tests, with negative results on ~~a~~ samples taken ~~during the~~ 30 days apart with the second sample taken within 10 days prior to shipment.

Article 12.10.6.

Recommendations for the importation of equine semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males ~~animals~~:

   a) showed no clinical signs of ~~glanders~~ *infection with B. mallei* on the day of collection; ~~and for the following 21 days;~~

   b) were examined clinically for signs of orchitis, with negative results;~~were kept continuously:~~

      ~~i) either for a period of at least 21 days prior to, and for until at least 21 days after, the collection in a country or a *zone* free from *infection* with *B. mallei*, or~~

      ~~ii) for at least six months prior to the collection of the semen and during the collection in an *establishment* or *artificial insemination centre* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen semen between 21 and 30 days after the collection;~~

2) the semen was collected, processed and stored in accordance with the relevant recommendations in Chapter 4.5. and in Articles 4.6.5. to 4.6.7.

Article 12.10.7.

Recommendations for the importation of *in vivo* derived equine embryos

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females ~~animals:~~

   ~~a)~~ showed no clinical signs of ~~glanders~~ *infection with B. mallei* on the day of collection ~~and for the following 21 days~~;

   ~~b) were kept continuously:~~

      ~~i) either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a *zone* free from *infection* with *B. mallei*, or~~

      ~~ii) for at least six months prior to the collection and during the collection in an *establishment* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;~~

2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9.~~, as relevant~~;

3) the semen used for embryo production ~~to fertilise the oocytes~~ complies with ~~the recommendations in~~ Article 12.10.6.

Article 12.10.8.

General Principles of surveillance

~~The purpose of *surveillance* is to determine the status of a country or a *zone* with respect to *infection* with *B. mallei*.~~

~~*Surveillance* should be carried out in accordance with Chapter 1.4.~~

~~Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through testing of roadkill or equids or culled as part of population control measures.~~

~~Clinical *surveillance* aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of *surveillance* contributing to the desired level of confidence of detection of *disease*, if so long as a sufficiently large number of clinically susceptible animals is examined. Laboratory investigations should be conducted on all suspected cases.~~

~~Systematic pathological *surveillance* is an effective approach for glanders and should be conducted on dead equids on farm, at *slaughterhouses/abattoirs* and establishments for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be typed.~~

~~When conducting serological *surveillance* repeated testing of the equine population is necessary to reach an acceptable level of confidence.~~

~~Clinical examination and laboratory testing should be applied to clarify the status of suspects detected by either of these complementary diagnostic approaches. Laboratory testing and necropsy may contribute to confirm clinical suspicion, while clinical examination may contribute to confirmation of positive serology.~~

This article and Article 12.10.9. provide recommendations for *surveillance* for glanders and are complementary to Chapter 1.4. The impact and epidemiology of glanders vary in different regions of the world. The *surveillance* strategies employed for determining glanders status should be adapted to the respective epidemiological situation.

The *surveillance* programme should be designed to demonstrate that susceptible populations in a country or *zone* show no evidence of *infection* with *B. mallei* or to detect its introduction into a free population. If *B. mallei* is known to be present, *surveillance* should allow the estimation of the *prevalence* and the determination of the distribution of the *infection*.

A *surveillance* system in accordance with Chapter 1.4 should be under the responsibility of the *Veterinary Authority* and should have in place:

a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* with appropriate testing capability for glanders diagnosis;

c) a system for recording, managing and analysing diagnostic, epidemiological and surveillance data;

d) established links with an OIE Reference Laboratory in case of need for confirmatory testing.

The glanders *surveillance* programme should include an *early detection system* for reporting suspected *cases*. Diagnosticians and those with regular contact with susceptible or infected equids should report promptly any suspicion of glanders to the *Veterinary Authority*. The reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government awareness programmes. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in glanders, epidemiological evaluation and control as part of their contingency plan.

The *Veterinary Authority* should implement, when relevant, regular and frequent clinical inspections and random or targeted serological surveys and laboratory testing of high-risk groups or those adjacent to a country or *zone* infected with *B. mallei*. An effective *surveillance* system is likely to identify suspected *cases* that require follow-up investigation to confirm or exclude that the cause of the condition is *B. mallei*. All suspected *cases* of *infection* with *B. mallei* should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for the *surveillance*. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the equids concerned were subjected during the investigation (quarantine, movement control).

Susceptible *captive wild*, *feral* and *wild* equine populations should be included in the *surveillance* programme.

Surveillance should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of *infection* with *B. mallei* in the absence of clinical signs.

Article 12.10.9.

Surveillance strategies

The strategy employed may be based on clinical investigation, or randomised or targeted sampling at an acceptable level of statistical confidence. If glanders is present, it is usually at a very low *prevalence*. If an increased likelihood of *infection* in particular geographical locations or *subpopulations* can be identified, targeted sampling is appropriate.

To detect *infection* or to determine the distribution and estimate the *prevalence* of *infection* either at the level of the entire population or within targeted *subpopulations*, the design of the sampling strategy and frequency of testing should incorporate epidemiologically appropriate design *prevalence* for the selected populations. The sample size selected for testing should be statistically relevant to detect the presence of *infection* if it were to occur at a predetermined minimum rate. The design *prevalence* and confidence level should be consistent with the objectives of the *surveillance* and the epidemiological situation.

To substantiate freedom from *infection* in a country or *zone*, *surveillance* should be conducted in accordance with the relevant provisions of Chapter 1.4. Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests employed should be considered in the design and in the interpretation of the results obtained. The occurrence of false positive reactions has to be considered and the rate at which these false positives are likely to occur should be calculated in advance. Every positive result should be investigated to determine whether it is indicative of *infection* or not. This involves supplementary tests, trace-back and trace-forward, and inspection of individual *animals* and *herds* for clinical signs. Laboratory results should be interpreted in the context of the epidemiological situation.

Methods should include clinical *surveillance* and laboratory testing. They should always be applied in series to clarify the status of suspected *cases* of glanders detected by either of these complementary diagnostic approaches. Agent identification should be carried out on any equid positive or showing clinical signs. Any *epidemiological unit* within which suspected *cases* are detected should be considered infected until contrary evidence is produced.

1. Clinical surveillance

   Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids. However, clinical *surveillance* is of limited use only as asymptomatic carrier animals are the main reservoir of the *disease*.

2. Pathological and bacteriological surveillance

   Systematic pathological *surveillance* is an effective approach for the detection of glanders and should be conducted on dead equids on farms, at *slaughterhouses/abattoirs* and facilities for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be characterised.

3. Serological surveillance

Serological *surveillance* for glanders is the preferred strategy. Repeated testing of the equid population with recommended tests is necessary to reach an acceptable level of confidence.

4. Malleinisation

Frequently used as a *surveillance* method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings that should be considered when interpreting results.

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